REMARKS

Claims 8-9, 14, 18-20 and 25 are pending in this application. No claims are herewith added or deleted. Thus, claims 8-9, 14, 18-20 and 25 are active in this case.

I. Claim Rejections - 35 USC § 103

The Examiner rejects claims 8, 9, 14, 18-20 and 25 under 35 U.S.C. 103(a) as being unpatentable over Kuehne *et al.* (CA 1268714) in view of Kern *et a*l. (US 5,712,097).

Kuehne is cited for stating that stabilized chlorite solution can be used to treat solid tumors such as adenocarcinoma. Kern is cited for teaching that primary pancreatic carcinoma is an adenocarcinoma that is associated with DCC. The examiner acknowledges that Kern does not teach the treatment of pancreatic carcinoma. Kern is cited only for teaching that pancreatic cancer is associated with DCC. The Examiner concludes that it would have been obvious to one of skill in the art to substitute pancreatic carcinoma for adenocarcinoma. The Examiner relies upon Wikipedia to support the assertion that the term adenocarcinoma is frequently associated with pancreatic cancer. In other words, the examiner argues that adenocarcinoma is the same as pancreatic cancer and that pancreatic cancer is the same as a cancer that is characterized by a reduced expression of the deleted in colorectal carcinoma (DCC). Thus, according to the Examiner, a suggestion to treat an adenocarcinoma renders obvious a suggestion to treat all cancers characterized by a reduced expression of the deleted colorectal carcinoma (DCC). Applicants respectfully but vigorously traverse this rejection.

The Examiner's rejection is based upon hindsight of knowing the invention, which is an impermissible basis for a rejection under § 103. Although most pancreatic carcinomas are adenocarcinomas, the reverse is not true: not all adenocarcinomas are pancreatic cancers. In fact, adenocarcinoma does not refer to any particular organ or body site. Rather adenocarcinoma is a type of cancer that evolves from a certain cell type found throughout the body. Specifically, the National Cancer Institute, defines adenocarcinoma as a cancer that begins in cells that line

certain internal organs and that have gland-like (secretory) properties. See http:www.cancer.gov/dictionary/?searchTxt=adenocarcinoma (copy attached). Some organs, like the lung, have adenocarcinomas and other types of carcinomas, such as squamous cell carcinomas or small cell carcinomas, which evolves from non-secretory type cells. Thus, the term adenocarcinoma is a class of cancers that covers a broad array of cancers from different organs and body sites.

The Examiner relies upon Wikipedia. Applicants do not agree that this is a proper scientific source. However, because the Examiner relied upon Wikipedia, applicants point out that Wikipedia lists several types of cancers as adenocarcinomas, including breast, colon, lung, prostate, stomach, pancreas, cervix, vagina, urachus (http://en.wikipedia.org/wiki/Adenocarcinoma). This list includes cancers of many different types. They involve different tissues, different prognoses and different treatments. Thus, Kuehne's teaching treating adenocarcinomas with a chlorite solution would not have given the skilled artisan an expectation of success in treating any particular types of cancer, including pancreatic cancer, with chlorite.

Additionally, applicants do not agree that the term "adenocarcinoma" would lead one to pancreatic cancer. As explained above, pancreatic cancer is just one type of adenocarcinoma. Why would one of skill in the art link adenocarcinoma with pancreatic cancer rather than some other type of cancer? There is not reason. The Examiner's rejection is based upon hindsight of knowing the invention.

In the same vein, one of skill in the art would not have been motivated to combine the references as applicant has done. Nothing in any of the cited references motivates such combining. Again, this rejection is made upon hindsight and not upon what the references actually teach or what the skilled artisan would have expected or have assumed.

In view of the above comments, applicants respectfully request the Examiner to reconsider and withdraw this rejection under 35 USC § 103.

CONCLUSION

Should the Examiner believe that anything further is necessary in order to place this application in better condition for allowance, the Examiner is requested to contact the undersigned at the telephone number listed below.

In the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account No. 01-2300 referencing docket number 029364.00002.

Respectfully submitted,

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Enclosures: Definition of Adenocarcinoma from NCI Dictionary of Cancer Terms
Wikipedia description of Adenocarcinoma

Dictionary of Cancer Terms

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adenocarcinoma (A-den-oh-KAR-sih-NOH-muh)

Cancer that begins in cells that line certain internal organs and that have gland-like (secretory) properties.

Previous Definitions: acute promyelocytic leukemia, acyclovir, AD 32, Adderall, addiction

Next Definitions: adenoid cystic carcinoma, adenoma, adenopathy, adenosine triphosphate, adenosquamous carcinoma

Adenocarcinoma

From Wikipedia, the free encyclopedia

Adenocarcinoma, NOS	
Classification & external resources	
ICD-9	151.0, 182.0
ICD-O:	M8140/3

Adenocarcinoma is a cancer that originates in glandular tissue. This tissue is also part of a larger tissue category known as epithelial tissue. Epithelial tissue includes skin, glands and a variety of other tissue that lines the cavities and organs of the body. Epithelial tissue is derived embryologically from ectoderm, endoderm and mesoderm. To be classified as adenocarcinoma, the cells do not necessarily need to be part of a gland, as long as they have secretory properties. This form of carcinoma can occur in some higher mammals, including humans.[1] Well differentiated adenocarcinomas tend to resemble the glandular tissue that they are derived from, while poorly differentiated may not. By staining the cells from a biopsy, a pathologist will determine whether the tumor is an adenocarcinoma or some other type of cancer. Adenocarcinomas can arise in many tissues of the body due to the ubiquitous nature of glands within the body. While each gland may not be secreting the same substance, as long as there is an exocrine function to the cell, it is considered glandular and its malignant form is therefore named adenocarcinoma. Endocrine gland tumors, such as a VIPoma, an insulinoma, a pheochromocytoma, etc, are typically not referred to as adenocarcinomas, but rather, are often called neuroendocrine tumors. If the glandular tissue is abnormal, but benign, it is said to be an adenoma. Benign adenomas typically do not invade other tissue and rarely metastasize. Malignant adenocarcinomas invade other tissues and often metastasize given enough time to do so.

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Diagnostic significance

A diagnosis of *adenocarcinoma* which is not further described, known as **adenocarcinoma not otherwise specified** and **adenocarcinoma NOS**, is significant because it indicates a cancerous process is present. However, it is not very useful for treatment decisions and prognosis, as these are determined by the tissue from which the tumour cells arose, i.e. the tissue of origin; an adenocarcinoma of the colon has a different prognosis and treatment than an adenocarcinoma of the ovary.

Adenocarcinoma not otherwise specified is often a preliminary diagnosis and can frequently be clarified by a pathologist with the use of immunohistochemistry.[2]

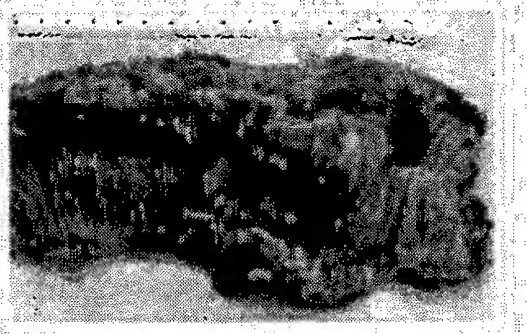
Cancer for which a primary site cannot be found is called **cancer of unknown primary**.

Gross and Histopathology of Selected Types of Adenocarcinoma

Examples of tissues where adenocarcinomas may arise:

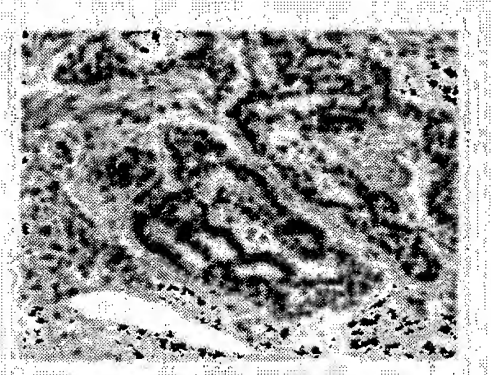
- **breast:**

- **colon:**
  The vast majority of colorectal cancer is an adenocarcinoma. This is because the colon had numerous glands within the tissue. Normal colonic glands tend to be simple and tubular in appearance with a mixture of mucus secreting goblet cells and water absorbing cells. These glands are called glands because they secrete a substance into the lumen of the colon, this substance being mucus. The purpose of these glands are two fold. The first is to absorb water from the feces back into the blood. The second purpose is to secrete mucus into the colon lumen to lubricate the now dehydrated feces. This is crucial as a failure to lubricate the feces can result in colonic damage by the feces as it passes towards the rectum. [3]



Gross appearance of a colectomy specimen containing two adenomatous polyps (the brownish oval tumors above the labels, attached to the normal beige lining by a stalk) and one **invasive colorectal carcinoma** (the crater-like, reddish, irregularly-shaped tumor located above the label).

When these glands undergo a number of changes as the genetic level, they proceed in a normal and predictable manner as they move from benign to an invasive, malignant colon cancer. In the research paper, Vogelstein, et al, suggested that colon cells lose the APC tumor suppressor gene and become a small polyp. Next, they suggested that k-Ras becomes activated and the polyp becomes a small, benign, adenoma. The adenoma, lacking the "carcinoma" attached to the end of it, suggests that it is a benign version of the malignant adenocarcinoma. The gastroenterologist uses a colonoscopy to find and remove these adenomas and polyps to prevent them from continuing to acquire genetic changes that will lead to an invasive adenocarcinoma. Volgelstein et al went on to suggest that loss of the DCC gene and of p53 result in a malignant adenocarcinoma. [4]



Histopathologic image of colonic carcinoid stained by hematoxylin and eosin.

Grossly, one will see a mass that looks of a different color than the surrounding tissue. Bleeding from the tumor is often apparent as the tumor tends to grow blood vessels into it in a haphazard manner via secretion of a number of angiogenesis promoting factors such as VEGF. Histologically, a glandular structure, similar to the healthy normal surrounding glands may be seen. If they look very similar, this is a low grade, well differentiated tumor. Often these glands will be disorganized and they will be seen growing back to back. However, if the tumor does not look like a gland anymore, it is a high grade tumor with poor differentiation. Regardless of the grade, malignant tumors tend to have a large nucleus with prominent nucleoli. There will also be a noticeable increase in the incidence of mitoses, or cell divisions.

- **lung:**

Currently, the most common type of lung cancer is the adenocarcinoma.[5] This cancer usually is seen peripherally in the lungs, as opposed to small cell lung cancer and squamous cell lung cancer, which

both tend to be more centrally located.[6] The adenocarcinoma has an increased incidence in smokers, but is also the most common type of lung cancer seen in non-smokers. Adenocarcinoma of the lung tends to stain mucin positive as it is derived from the mucus producing glands of the lungs. Similar to other adenocarcinoma, if this tumor is well differentiated (low grade) it will resemble the normal glandular structure. Poorly differentiated adenocarcinoma will not resemble the normal glands (high grade) and will be detected by seeing that they stain positive for mucin (which the glands produce).[7] [[1]]

- **prostate:**

- **stomach:**

- **pancreas:** (99% of pancreatic cancers are ductal adenocarcinomas[8])
- **cervix:**

- **vagina:**

- **urachus:**

Origin of term

The term adenocarcinoma is derived from 'adeno' meaning 'pertaining to a gland' and 'carcinoma', which describes a cancer that has developed in the epithelial cells.

References

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